PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100851-1 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE 03/02088	International filing date *(day/month/year)* 29.12.2003	Priority date *(day/month/year)* 07.01.2003
International Patent Classification (IPC) or both national classification and IPC C07D333/10		
Applicant ASTRAZENECA AB et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.07.2004	14.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Boletti-Cremers, K Telephone No. +49 89 2399-8541

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE 03/02088

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-81 as originally filed

Claims, Numbers

1-19 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 16

because:

☒ the said international application, or the said claims Nos. 16 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-19 (with proviso)
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-19
Industrial applicability (IA)	Yes:	Claims	1-15,17-19
	No:	Claims	

2. Citations and explanations

see separate sheet

POINT III.

For the assessment of the presently worded claim 16, on the question whether it is industrially applicable, no unified criteria exist in the PCT.
The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognise as industrially applicable claims to the use of a compound in medical treatment; but will allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a new medical treatment.

POINT V.

The following documents , quoted in the I.S.R., have been considered as relevant for the examination of the present application . Their numbering will be adhered to for the rest of the procedure.

(1) Chemistry and physics of lipids, vol. 121, 2002, pages 3 - 19.
(2) Chemistry and physics of lipids, vol. 121, 2002, pages 191 - 200.

1. Novelty.

In view of the fact that both documents relate to CB_1/CB2 receptors which fall mainly within the scope of present claim 1, said claim and any dependent claim which is based upon present claim 1 lack novelty.
Indeed , the compounds identified in (1) and (2) as SR-141716A , SR-144528, AM-251 and AM281 (see their formulas as on page 11 of (1)) all fall whithin the scope of at least present claim 1 in that they possess particular definitions belonging to the open ended scope of present claim 1 which should be restricted so as to enable a clear and unambiguous acknowledgment of the novelty towards the contents of those 2 documents, bearing the following in mind.
Provided claim 1 would be rendered novel in the regional proceedings to come , all the claims depending on claim 1 could also be regarded as novel (see also the lack of clarity point 3.2 of present communication)

2. Inventiveness.

In view of the fact that both (1) and (2) already disclose solutions to the problem of providing CB1/CB2 receptors , both documents constitute the most relevant prior art in the state of the file , which (reminder) has not been fully searched.

Insofar as those documents already provided solutions to the above named problem , solutions which belong to presently claimed matter in its broadest sense , the Applicant is invited to show either by argumentation or technical evidence , that the still novel compounds on file possess any advantage or surprising feature when they are compared with those of (1) and (2) in order to enable the acknowledgment of the inventiveness of the application with respect to the content of the most relevant prior art.
Moreover , he is invited to restrict the claimed matter to preferred embodiments which would enable the acknowledgment of the inventiveness **and** a possible additional exhaustive search of the full extension of protection desired.
Such an additional search will be then be performed in the (regional) future.

3. Formal Points.

3.1 Documents (1) and (2) should be mentioned and briefly discussed in the description.

3.2 Claim 1 is unclear in scope in that it seems that the 2 aryl (Ar^2) and arylene (Ar^1) radicals have to be separated by at least one atom, which is not the case in all the examples . As transpires from the above novelty objections , the IPEA assumed that no atoms are linking the 2 Ar radicals .
The Applicant is invited to reformulate the claims so as to enable a clear interpretation of the desired scope of protection.